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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,487	01/04/2002	Nannette M. VanAntwerp	PD-0268 DIV 2	6491
23608	7590	08/02/2006	EXAMINER	
MEDTRONIC MINIMED INC. 18000 DEVONSHIRE STREET NORTHRIDGE, CA 91325-1219			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/038,487	VANANTWERP ET AL.
	Examiner	Art Unit
	Andrew M. Gilbert	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 June 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36-59 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 6/15/2006.
2. In the reply, the applicant correctly renumbered the claims. No amendments to the claims were made. Thus, claims 36-59 are pending.
3. In the reply, the applicant provided the proper reference to prior applications by amending the first sentence of the specification. Thus, priority to these prior applications has been accepted.
4. Additionally, the applicant provided proper citation of the divisional application transmittal letter dated January 4, 2002 that provides the title of the invention being "Insertion set for a transcutaneous sensor with cable connector lock mechanism". Thus, the objection to the title is withdrawn.
5. Finally, the applicant filed a terminal disclaimer to US Pat No. 5954643 that has been approved. Thus, the nonstatutory obviousness-type double patenting rejection to claims 36-59 has been withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 36-39, 41-44, 46-51, 53-56, and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Balbierz (4840613). Balbierz discloses an

insertion set (Fig 1) having a mounting base (52); an infusion tubing (36), wherein the infusion tubing includes a connector (62); a cannula (12) coupled to the mounting base (52; Fig 1), wherein the cannula has a distal end protruding from the mounting base (14; Fig 1); the cannula is in fluid communication with the infusion tubing (18; Fig 1); an insertion needle (17) having a distal end protruding from the mounting base (17; Fig 1), wherein the insertion needle surrounds the inside of the cannula (Fig 1), and the insertion needle is withdrawable from the mounting base after the cannula is placed at the selected insertion site (col 12, Ins 26-39); and an adhesive patch (col 7, Ins 25-27) attached to an underside surface of the mounting base; wherein the connector includes a pair of recesses (62, 64), and the mounting base includes a pair of resilient latch arms (58, 60) rearwardly projecting from the mounting base and adapted for snap-fit, releasable engagement with the pair of recesses on the connector (Fig 1, 4); and wherein the at least one lumen of the cannula is also adapted for withdrawing fluid from the patient (col 8, Ins 32-35).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 40, 45, 52, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz (4840613) in view of Lord et al (5390671). Balbierz discloses the invention substantially as claimed except for wherein the cannula further

includes at least one lumen for receiving at least a portion of a flexible sensor, the sensor having a distal segment protruding from the mounting base with at least one sensor electrode. Lord et al teaches that it is known to have wherein the cannula further includes at least one lumen for receiving at least a portion of a flexible sensor therein, the sensor having a distal segment protruding from the mounting base (Figs 1-3) with at least one sensor electrode for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate blood chemistry readings can be taken. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor as taught by Balbierz with the sensor as taught by Lord et al for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate blood chemistry readings can be taken.

Response to Arguments

10. Applicant's arguments filed 6/15/2006 have been fully considered but they are not persuasive.

11. In the reply, the applicant argues:

- i. Balbierz does not disclose "an insertion set for use with infusion tubing having a connector with at least one recess on the connector adapted for coupling the infusion tubing to the insertion set..." (Remarks, pg 11, paragraph 4)
- ii. The sheath (36) is never described as infusion tubing and the sheath has a longitudinal slit (41) allowing sheath to be stripped away thus there

is no possible way fluid can pass through the sheath (36) in the same way that fluid passes through the infusion tubing (Remarks, pg 12, paragraphs 2-3)

iii. Second lock member (62) is not the same as the connector disclosed because the second lock member slides over the sheath and is not physically connected to the hub structure (Remarks, pg 13, paragraph 1)

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the sheath (36) much pass fluid through the infusion tubing in the same way as the Applicant's invention; that the connector (62) cannot be the same as the disclosed connector because it slides about the sheath and is free of connection with the hub structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

13. In response to applicant's arguments, the recitation "an insertion set for use with infusion tubing having a connector with at least one recess on the connector adapted for coupling the infusion tubing to the insertion set" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). If the Applicant wishes to give more patentable weight to the recitation, the Examiner suggests moving the recitation to the body of the claim after the recitation of "the insertion set comprising".

14. In response to applicant's argument (ii), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the sheath (36) does not necessarily have to be stripped and the longitudinal slit (41) can remain closed. In that case, the sheath (36) is fully capable of performing the intended use of the infusion tubing of being adapted for delivering fluid through the connector to the insertion set.

15. In response to applicant's argument (iii), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the applicant is relying on limitations from the specification not read into the claims and the Examiner notes that the connector (62) is fully capable of performing the intended use functions of coupling the infusion tubing to the insertion set. The applicant has not recited in the claims that the connector is attached in a fixed position to one end of the infusion tubing and/or connector cables.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

